

REMARKS

Claims 1-17 and 22-40 are pending in the application with claims 1, 8, 13, 14, 22-24, and 27 being the independent claims. Claims 1, 8, 13, 14, and 23 are amended. Support for these claim amendments and new claims can be found in the specification, claims, and drawings as originally filed. Applicant traverses the rejections.

Office Action Dated September 20, 2007

The Office Action dated September 20, 2007 shows claim status inconsistencies in the Office Action Summary page and the Detailed Action section. In a telephone discussion with the Examiner on October 15, 2007, the Examiner explained that the Detailed Action section represents the intended status of the claims. Accordingly, this paper responds to the Office Action as clarified by the telephone discussion.

Allowed Claim

Applicants acknowledge the indication that claim 27 is allowed.

Compliance with 35 U.S.C. §102

The Office Action indicated that claims 1-7, 11, 14-17, 22-26, and 28-38 are rejected under 35 U.S.C. §102(e) as being anticipated by FR 724 108 to Francois. In a telephone discussion with the Examiner on November 14, 2007, the Examiner indicated that the correct number for the applied French reference is FR 2 721 108 (“FR ’108 reference”).

Applicants note that claims 28-38 are identified as being anticipated although their respective base claims (claims 8 and 13) are rejected as being obvious under §103.

Independent Claim 1

By this paper, claim 1 is amended to further define the first and second flanges recited in claim 1. Claim 1 is directed to a prosthetic device for lateral insertion. In particular, claim 1 recites:

A prosthetic device for lateral insertion into an intervertebral space, comprising

a first component having a width sized to extend in a substantially posterior-anterior direction within the intervertebral space, and a length sized to extend in a lateral direction within the intervertebral space, the length being greater than the width, the first component including a first laterally-extending flange extending generally in the lateral direction of the width and configured to advance into a laterally extending preformed opening in a first vertebra from a lateral approach, the first flange extending from a first bearing surface offset from a first center point of the first bearing surface, the first flange including a portion adjacent the bearing surface and a top-most portion spaced from the bearing surface, the top-most portion laterally extending along a substantial portion of the first flange, the first component having a first articular surface opposite the first bearing surface, and

a second component having a width sized to extend in a substantially posterior-anterior direction within the intervertebral space, and a length sized to extend in a lateral direction within the intervertebral space, the length being greater than the width, the second component including a second laterally-extending flange for engaging a second vertebra from a lateral approach, the second flange extending generally in the lateral direction of the width and extending from a second bearing surface offset from a second center point of the second bearing surface, the second flange including a portion adjacent the bearing surface and a bottom-most portion spaced from the bearing surface, the bottom-most portion laterally extending along a substantial portion of the second flange, the second component having a second articular surface opposite the second bearing surface for cooperating with the first articular surface to permit articulating motion between the first and second components.

The FR '108 reference does not anticipate claim 1 because it fails to disclose all the features recited in claim 1. For example, the FR '108 reference fails to disclose a prosthetic device for lateral insertion in a disc space. Instead, it appears to discloses a prostheses for an ankle. As an initial matter, an ankle is not an intervertebral space and an ankle prosthesis does not include a "flange configured to advance into a laterally extending preformed opening in a first vertebra from a lateral approach."

In addition, by this paper, Applicants amend claim 1 to recite that the first and second components have "a width sized to extend in a substantially posterior-anterior direction within

the intervertebral space, and a length sized to extend in a lateral direction within the intervertebral space, the length being greater than the width” and a “flange extending generally in the lateral direction of the width.” The FR ’108 reference does not disclose these claimed features and therefore cannot anticipate claim 1.

Fig. 5 of the FR ’108 reference discloses flanges extending along a length of the device, where the length is shorter than a width. This is the opposite of that claimed. Because the cited prior art reference fails to disclose all the features of claim 1, Applicants submit that claim 1 is in condition for allowance. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Independent Claim 14

By this paper, claim 14 is amended to further define the first and second flanges recited in claim 14. Claim 14 is directed to a prosthetic device for lateral insertion. In particular, claim 14 recites:

14. A prosthetic device for lateral insertion into an intervertebral space, comprising

a first component having a single first laterally-extending flange for engaging a first vertebra from a lateral approach, the first flange extending from a first bearing surface offset from a first center point of the first bearing surface, the first component having a first articular surface opposite the first bearing surface, and

a second component having a single second laterally-extending flange for engaging a second vertebra from a lateral approach, the second flange extending from a second bearing surface offset from a second center point of the second bearing surface, the second component having a second articular surface opposite the second bearing surface for cooperating with the first articular surface to permit articulating motion between the first and second components, wherein the first component comprises a projection extending from the first articular surface.

The FR ’108 reference does not anticipate claim 14 because it fails to disclose all the features recited in claim 14. For example, the FR ’108 reference fails to disclose a prosthetic device for lateral insertion in an intervertebral space. Instead, it appears to disclose a prosthesis for an ankle. As an initial matter, an ankle is not an intervertebral space and an ankle prosthesis does not include a “laterally-extending flange for engaging a first vertebra from a lateral approach.”

In addition, by this paper, claim 14 is amended to recite a first component and a second component each having a “single” flange “offset from a [] center point of the [] bearing surface.” The ’FR 108 patent does not disclose any device having these features. Because the cited prior art reference fails to disclose all the features of claim 14, Applicants submit that claim 14 is in condition for allowance. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Independent Claim 22

Claim 22 is directed to a prosthetic device for lateral insertion. In particular, claim 22 recites:

A prosthetic device for insertion into an intervertebral space defined between a pair of spondylosed vertebrae, comprising:
a first component, comprising:

a first flange laterally extending along a first bearing surface, the first flange including a first portion adjacent the bearing surface and a second portion spaced from the bearing surface, the second portion laterally extending along a substantial portion of the first flange; and

a projection extending from a first articular surface; and
a second component adapted to be engaged with the first component, comprising:

a second flange laterally extending along a second bearing surface, the second flange including a first portion adjacent the bearing surface and a second portion spaced from the bearing surface, the second portion laterally extending along a substantial portion of the second flange, the second flange being offset from the first flange and the second bearing surface being substantially parallel to the first bearing surface during engagement of the second component with the first component, thereby accommodating a spondylosed relationship between a first vertebra and a second vertebra; and

a recess formed in the second articular surface;
wherein the projection and the recess engage one another to provide for articulating motion between the first and second components.

The FR ’108 reference does not anticipate claim 22 because it fails to disclose all the features recited in claim 22. For example, the FR ’108 reference fails to disclose a prosthetic device for insertion into an intervertebral space defined between vertebrae and a device that “accommodate[es] a spondylosed relationship between a first vertebra and a second vertebra.”

In addition, the FR '108 reference fails to disclose any first components with a first flange and a second component with a second flange, with “the second flange being offset from the first flange and the second bearing surface being substantially parallel to the first bearing surface during engagement of the second component with the first component.” Instead, as shown in Figs. 1-3 of the FR '108 reference, when the surfaces that interface with the tibia and other bones are parallel, the flanges are not offset. Instead, they appear as though they would be aligned. Accordingly, the claimed feature of “the second flange being offset from the first flange and the second bearing surface being substantially parallel to the first bearing surface during engagement of the second component with the first component,” is not present in the FR '108 reference.

Because the cited prior art reference fails to disclose all the features of claim 22, Applicants submit that claim 22 is in condition for allowance. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Independent Claim 23

By this paper, claim 23 is amended to further define the flange. Claim 23 is directed to a prosthetic component. In particular, claim 23 recites:

A prosthetic component for forming a portion of a prosthetic device, comprising a first surface having a single flange formed thereon, the flange configured to advance into a laterally extending preformed opening in a vertebra from a lateral approach, the flange including a first portion adjacent the first surface and a second portion spaced from the first surface, the second portion laterally extending along a substantial portion of the flange, the flange being offset from a center point of the first surface, and a second surface in an opposed relation to the first surface, the second surface being adapted to engage another prosthetic component.

The FR '108 reference does not anticipate claim 23 because it fails to disclose all the features recited in claim 23. For example, the FR '108 reference fails to disclose a component having “a single flange formed thereon, the flange configured to advance into a laterally extending preformed opening in a vertebra from a lateral approach.” Instead, the device in the FR '108 patent discloses two flanges and does not appear to disclose that they are “configured to

advance into a laterally extending preformed opening in a vertebra from a lateral approach," as required by claim 23.

Because the cited prior art reference fails to disclose all the features of claim 23, Applicants submit that claim 23 is in condition for allowance. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Independent Claim 24

Independent claim 24 is directed to a method for inserting a prosthetic device into an intervertebral space from a lateral approach: Specifically, it recites:

24. A method for inserting a prosthetic device into an intervertebral space from a lateral approach, comprising

providing a prosthetic device having a first articular component and a first flange extending laterally along a surface of the first articular component, and a second articular component and a second flange extending laterally along a surface of the second articular component, and

laterally inserting the first articular component into a first vertebra, and laterally inserting the second articular component into a second vertebra such that the second flange is offset with respect to the first flange and the surfaces of the first and second components are substantially parallel, the second vertebra being adjacent to the first vertebra.

Applicants submit that the FR '108 reference does not anticipate claim 24 because it fails to disclose all the features recited in claim 24. For example, the FR '108 reference fails to disclose "inserting a prosthetic device into an intervertebral space from a lateral approach" as recited in the preamble, fails to disclose "laterally inserting the first articular component into a first vertebra," and fails to disclose "laterally inserting the second articular component into a second vertebra" with "the second vertebra being adjacent to the first vertebra," as recited in claim 24. The FR '108 reference appears to discloses a device for implantation in an ankle – not a prosthetic device for insertion into an intervertebral space from a lateral approach. An ankle and a vertebra with a disc space are not only at different locations in the body, but they function differently and interface with bones in different ways. Accordingly, Applicants submit that the method of claim 24 is allowable over the FR '108 reference.

Compliance with 35 U.S.C. §103

The Office Action indicated that claims 8-10, 12, 13, 39, and 40 are rejected under 35 U.S.C. §103 as being unpatentable over the combination of the FR '108 reference in view of U.S. Patent No. 7,056,344 to Huppert et al. ("Huppert").

Independent Claim 8

By this paper, claim 8 is amended to further define the prosthetic device. Claim 8 is directed to a prosthetic device for lateral insertion into an intervertebral space. In particular, claim 8 recites:

8. A prosthetic device for lateral insertion into an intervertebral space, comprising

a first component having a first laterally-extending flange for engaging a first vertebra from a lateral approach, the first flange extending from a first bearing surface offset to one side of a first center point of the first bearing surface, the first bearing surface being devoid of a flange on the other side of the first center point of the first bearing surface, the first component having a first articular surface opposite the first bearing surface, and

a second component having a second laterally-extending flange for engaging a second vertebra from a lateral approach, the second flange extending from a second bearing surface offset to one side of a second center point of the second bearing surface, the second bearing surface being devoid of a flange on the other side of the second center point of the second bearing surface, the second component having a second articular surface opposite the second bearing surface for cooperating with the first articular surface to permit articulating motion between the first and second components, wherein the first and second flanges each comprise at least one hole therethrough.

The combination of the FR '108 reference and the Huppert patent does not establish a *prima facie* case of obviousness because the combination fails to teach or suggest all the features recited in claim 8. For example, claim 8 is directed to a prosthetic device having first and second components that include respective first and second flanges "extending from a [] bearing surface offset to one side of a [] center point of the [] bearing surface, the [] bearing surface being devoid of a flange on the other side of the [] center point of the [] bearing surface." This is not taught or suggested in the cited references. The FR '108 reference teaches two flanges equally spaced on opposing sides of a center point. Thus, there is no flange offset to one side of a center point of a

bearing surface with the bearing surface being devoid of a flange on the other side of the center point of the bearing surface. Likewise, the Huppert patent fails to teach or suggest any offset flange. Because the combination of prior art references fails to teach or suggest all the features of claim 8, claim 8 is allowable over the cited combination. Applicants respectfully request that the Examiner withdraw the rejection and allow this claim.

Independent Claim 13

By this paper, claim 13 is amended to further define the prosthetic device. Claim 13 is directed to a prosthetic device for lateral insertion into an intervertebral space. In particular, claim 13 recites:

13. A prosthetic device for lateral insertion into an intervertebral space, comprising

a first component having a first laterally-extending flange for engaging a first vertebra from a lateral approach, the first flange extending from a first bearing surface offset to one side of a first center point of the first bearing surface, the first bearing surface being devoid of a flange on the other side of the first center point of the first bearing surface, the first component having a first articular surface opposite the first bearing surface, and

a second component having a second laterally-extending flange for engaging a second vertebra from a lateral approach, the second flange extending from a second bearing surface offset to one side of a second center point of the second bearing surface, the second bearing surface being devoid of a flange on the other side of the second center point of the second bearing surface, the second component having a second articular surface opposite the second bearing surface for cooperating with the first articular surface to permit articulating motion between the first and second components, wherein the first and second components each comprise at least one notch formed laterally therein for receiving a surgical instrument.

The combination of the FR '108 reference and the Huppert patent does not establish a *prima facie* case of obviousness because the combination fails to teach or suggest all the features recited in claim 13. For example, claim 13 is directed to a prosthetic device having first and second components that include respective first and second flanges "extending from a [] bearing surface offset to one side of a [] center point of the [] bearing surface, the [] bearing surface being devoid of a flange on the other side of the [] center point of the [] bearing surface." This is not taught or suggested in the cited references. The FR '108 reference teaches two flanges

equally spaced on opposing sides of a center point. Thus, there is no flange offset to one side of a center point of a bearing surface with the bearing surface being devoid of a flange on the other side of the center point of the bearing surface. Likewise, the Huppert patent fails to teach or suggest any offset flange. Because the combination of prior art references fails to teach all the features of claim 13, Applicants submit that claim 13 is allowable over the cited combination. Applicants respectfully request that the Examiner withdraw the rejection and allow this claim.

Dependent Claims 2-7, 9-12, 15-17, 25, 26, and 28-40

Claims 2-7, 9-12, 15-17, 25, 26, and 28-40 each depend from and add additional features to one of the independent claims discussed above. Therefore, these claims are allowable for at least the reasons that the respective independent claims should be allowable. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection and allow these claims.

Conclusion

For at least the reasons set forth above, Applicant submits that the pending claims 1-17 and 22-40 are in condition for allowance. Accordingly, Applicant respectfully requests that the Examiner withdraw the outstanding rejections and issue a formal notice of allowance.

The Office Action and prior Office Actions contain characterizations of the claims and the related art to which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

Please grant any extension of time required to enter this response and charge any additional required fees, including claim fees, to our Deposit Account No. 08-1394.

Respectfully submitted,



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